

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MICHIGAN  
SOUTHERN DIVISION**

ASSOCIATION OF AMERICAN  
PHYSICIANS & SURGEONS,

Plaintiff,

V.

FOOD & DRUG ADMINISTRATION; DR. STEPHEN M. HAHN, Commissioner of Food & Drugs, in his official capacity; BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY; GARY L. DISBROW, Ph.D., Acting Director, Biomedical Advanced Research & Development Authority, in his official capacity; DEPARTMENT OF HEALTH & HUMAN SERVICES; and ALEX AZAR, Secretary of Health & Human Services, in his official capacity,

Defendants.

No. 1:20-cv-00493-RJJ-SJB

Hon. Robert J. Jonker

Mag. Sally J. Berens

## Oral Argument Requested

**COMBINED REPLY IN SUPPORT OF PLAINTIFF’S MOTION  
FOR A PRELIMINARY INJUNCTION AND OPPOSITION TO  
DEFENDANTS’ MOTION TO DISMISS**

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## **TABLE OF CONTENTS**

Table of Authorities .....	iii
Introduction .....	1
Standard of Review .....	8
Argument.....	9
I. This Court has jurisdiction over this action.....	10
A. AAPS has standing. ....	10
1. Not all widely shared grievances are nonjusticiable. ....	11
2. AAPS has standing in its own right. ....	11
3. AAPS has associational standing. ....	12
a. FDA’s actions have caused redressable injuries to doctors and patients.....	13
b. AAPS need not identify its members. ....	16
c. Withholding Dr. Doe’s identity is easily cured. ....	19
4. AAPS has third-party standing for its physician members. ....	20
5. Physicians – and thus AAPS – have standing to assert patients’ rights. ....	20
B. Even if APA review were unavailable, the APA’s waiver of sovereign immunity would authorize non-APA review.....	21
C. This action is not moot. ....	21
1. This Court can vacate or modify FDA’s rescission. ....	22
2. Statements in FDA’s rescission would remain reviewable, even if rescission itself were moot. ....	22
II. AAPS states claims on which this Court can grant relief.....	23
A. FDA’s actions are reviewable. ....	24

1. The relevant statutes do not bar APA review.....	24
2. The relevant statutes do not bar pre-APA review. ....	25
3. The relevant statutes do not bar constitutional review.....	26
B. Whether under the APA or pre-APA review, FDA’s actions were improper.....	26
1. FDA acted arbitrarily and capriciously. ....	27
2. FDA exceeded its statutory authority.....	29
a. FDA lacks statutory authority for its clinical-trial requirement.....	30
b. FDA lacks statutory authority to limit off-label uses, based on perceived safety.....	31
3. FDA’s actions are “not in accordance with the law.” .....	32
C. AAPS states a claim under the First and Fifth Amendments. ....	33
1. Defendants’ actions chill First Amendment rights.....	33
2. Defendants violated the Due Process Clause’s Equal Protection component.....	35
D. A court can grant relief – and especially interim relief – on claims outside the pleadings.....	38
III. AAPS is entitled to a preliminary injunction.....	39
A. If this Court’s rejects FDA’s procedural defenses, this Court should grant interim relief because FDA has not otherwise disputed AAPS’s entitlement to that relief.....	40
B. FDA’s interference with HCQ correlates with anti-life policies in other countries, contrary to President Trump’s position.....	45
Conclusion .....	47

## TABLE OF AUTHORITIES

### CASES

<i>Allen v. Wright</i> , 468 U.S. 737 (1984) .....	22
<i>Arenas v. United States</i> , 322 U.S. 419 (1944) .....	25
<i>Ass’n of Am. Physicians &amp; Surgs. v. Tex. Med. Bd., (TMB)</i> , 627 F.3d 547 (5th Cir. 2010) .....	13
<i>Bates v. Green Farms Condo. Ass’n</i> , 958 F.3d 470 (6th Cir. 2020) .....	41
<i>Bemis Brothers Bag Co. v. U.S.</i> , 289 U.S. 28 (1933) .....	38
<i>Block v. Meese</i> , 793 F.2d 1303 (D.C. Cir. 1986).....	27
<i>Chamber of Commerce of the United States v. Reich</i> , 74 F.3d 1322 (D.C. Cir. 1996).....	25
<i>Columbia Broadcasting System, Inc. v. U.S.</i> , 316 U.S. 407 (1942) .....	15
<i>Colvin v. Caruso</i> , 605 F.3d 282 (6th Cir. 2010) .....	40
<i>Crossen v. Breckenridge</i> , 446 F.2d 833 (6th Cir. 1971) .....	20-21
<i>Ctr. for Bio-Ethical Reform, Inc. v. Napolitano</i> , 648 F.3d 365 (6th Cir. 2011) .....	36
<i>D.C. Fed’n of Civic Ass’ns v. Volpe</i> , 459 F.2d 1231 (D.C. Cir. 1971).....	28
<i>Democratic Party of United States v. Wisconsin</i> , 450 U.S. 107 (1981) .....	34
<i>Duncan v. Muzyn</i> , 833 F.3d 567 (6th Cir. 2016) .....	25
<i>F.C.C. v. Beach Commc’ns, Inc.</i> , 508 U.S. 307 (1993) .....	28

<i>Fed’l Election Comm’n v. Akins</i> , 524 U. S. 11 (1998) .....	11
<i>Fednav, Ltd. v. Chester</i> , 547 F.3d 607 (6th Cir. 2008) .....	16
<i>Frazier v. United States</i> , 335 U.S. 497 (1948) .....	26
<i>FW/PBS, Inc. v. Dallas</i> , 493 U.S. 215 (1990) .....	17
<i>Griffin v. Cty. Sch. Bd.</i> , 377 U.S. 218 (1964) .....	39
<i>Harkless v. Brunner</i> , 545 F.3d 445 (6th Cir. 2008) .....	12
<i>Hunt v. Washington Apple Advertising Comm’n</i> , 432 U.S. 333 (1977) .....	12
<i>Int’l Union v. Brock</i> , 477 U.S. 274, 284 (1986) .....	12
<i>June Med. Servs. L.L.C. v. Russo</i> , 207 L.Ed.2d 566 (U.S. 2020) .....	17
<i>Kowalski v. Tesmer</i> , 543 U.S. 125 (2004) .....	20
<i>Lexmark Int’l, Inc. v. Static Control Components, Inc.</i> , 572 U.S. 118 (2014) .....	10
<i>Lockhart v. Leeds</i> , 195 U.S. 427 (1904) .....	38
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992) .....	10
<i>Matthew N. Fulton, D.D.S., P.C. v. Enclarity, Inc.</i> , 962 F.3d 882 (6th Cir. 2020) .....	8-9
<i>Mich. State AFL-CIO v. Schuette</i> , 847 F.3d 800 (6th Cir. 2017) .....	12
<i>Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto Ins. Co.</i> , 463 U.S. 29 (1983) .....	28
<i>N.Y. State Club Ass’n, Inc. v. New York</i> , 487 U.S. 1 (1988) .....	21

<i>Nat’l Rifle Ass’n of Am. v. Magaw</i> , 132 F.3d 272 (6th Cir. 1997) .....	16
<i>People for the Ethical Treatment of Animals, Inc., v. Gittens</i> , 396 F.3d 416 (D.C. Cir. 2005).....	38
<i>Robinson v. Wash. Metro. Area Transit Auth.</i> , 774 F.3d 33 (D.C. Cir. 2014).....	44
<i>S. Bay United Pentecostal Church v. Newsom</i> , 140 S. Ct. 1613 (2020) .....	43
<i>Saieg v. City of Dearborn</i> , 641 F.3d 727 (6th Cir. 2011) .....	35
<i>SEC v. Chenery Corp.</i> , 318 U.S. 80 (1943) .....	28
<i>Summers v. Earth Island Institute</i> , 555 U.S. 488 (2009) .....	16-18, 20
<i>United States v. City of Detroit</i> , 25 F. App’x 384 (6th Cir. 2002).....	21
<i>United States v. Windsor</i> , 570 U.S. 744 (2013) .....	11
<i>Utica Packing Co. v. Block</i> , 781 F.2d 71 (6th Cir. 1986) .....	28
<i>Waskul v. Washtenaw Cty. Cmty. Mental Health</i> , 900 F.3d 250 (6th Cir. 2018) .....	19
<i>Webster v. Doe</i> , 486 U.S. 592 (1988) .....	26
<i>Winter v. NRDC, Inc.</i> , 555 U.S. 7 (2008) .....	41

## **STATUTES**

U.S. CONST. art. III.....	10, 12, 22
U.S. CONST. amend. I.....	12, 33-34
U.S. CONST. amend. V .....	33
U.S. CONST. amend. V, cl. 4 .....	35
Administrative Procedure Act, 5 U.S.C. §§551-706 .....	21, 23-26, 28-29

5 U.S.C. § 701(a) .....	24
5 U.S.C. § 701(a)(2).....	26
Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-399i .....	27-28, 31
21 U.S.C. § 355(b) .....	31
21 U.S.C. § 360bbb-3 .....	25
21 U.S.C. § 360bbb-3(d).....	30
21 U.S.C. § 360bbb-3(e)(1)(A)(i) .....	30
21 U.S.C. § 360bbb-3(e)(1)(A)(ii).....	30
21 U.S.C. § 360bbb-3(e)(1)(B)(2) .....	30
21 U.S.C. § 360bbb-3(e)(1)(B)(iii) .....	30-31
21 U.S.C. § 360bbb-3(e)(1)(B)(iv) .....	30
21 U.S.C. § 360bbb-3(e)(2) .....	30
21 U.S.C. § 360bbb-3(e)(2)(A).....	30-31
21 U.S.C. § 360bbb-3(e)(2)(B) .....	30
21 U.S.C. § 360bbb-3(e)(2)(C) .....	26-27, 30
21 U.S.C. § 360bbb-3(i).....	25
42 U.S.C. § 247d-6b.....	33
42 U.S.C. § 18116.....	32
42 U.S.C. § 18116(a) .....	33

## **RULES AND REGULATIONS**

FED. R. CIV. P. 15(b) .....	38-39
FED. R. CIV. P. 54(c).....	38
45 C.F.R. § 92.4 .....	32
59 Fed. Reg. 59,820 (Nov. 18, 1994) .....	32

## **OTHER AUTHORITIES**

Cardiologist weighs in on risks, benefits of using hydroxychloroquine to treat COVID-19, FOX NEWS (Apr. 24, 2020) .....	2-3
--	-----

Linda Carroll, <i>Declining numbers of Americans have a primary care provider</i> , REUTERS (Dec. 16, 2019).....	37
Danish Medicine Agency, <i>COVID-19: Facts about chloroquine and hydroxychloroquine</i> (Apr. 7, 2020) .....	46
Kenneth Culp Davis, <i>Nonreviewable Administrative Action</i> , 96 U. PA. L. REV. 749 (1948) .....	25
Nicholas Florko, <i>Why was an obscure federal bureaucrat involved in Trump’s emergency hydroxychloroquine authorization?</i> STAT NEWS (Apr. 24, 2020) .....	29
Maria Godoy, <i>Black Medicare Patients With COVID-19 Nearly 4 Times As Likely To End Up In Hospital</i> , NPR (June 22, 2020).....	37
Henry Ford Health System, <i>Treatment with Hydroxychloroquine Cut Death Rate Significantly in COVID-19 Patients, Henry Ford Health System Study Shows</i> (July 2, 2020).....	2
Bruce Japsen, <i>Poll: 44% Of Americans Skip Doctor Visits Because Of Cost</i> , FORBES (Mar 26, 2018).....	37
<i>Polish chemists show how to cheaply synthesise drug used to treat COVID-19</i> , THE FIRST NEWS (Mar. 26, 2020) .....	46

## **INTRODUCTION**

In this lawsuit against Defendants' interference with access to hydroxychloroquine (HCQ) to treat COVID-19, their opposition brief says nothing in substantive defense of their conduct. Less than 10% of their brief even mentions Plaintiff's pending motion for a preliminary injunction. Instead, Defendants argue that Plaintiff somehow lacks standing and a cause of action to challenge Defendants' waste of the HCQ in the Strategic National Stockpile ("Stockpile"), their false statements upon which States rely to block HCQ access, and their related wrongful conduct. Nearly everyone is affected by the COVID-19 pandemic and Defendants' interference with medication for it.

Absent from Defendants' brief is any assertion that President Trump could override Defendants, who are irrationally defying his promotion of HCQ. Defendants criticize AAPS for seeking relief on Trump's side, but legal redress should be available here as it has been for many lawsuits against Trump policies.

Plaintiff's members and the entire public are being denied early access to safe, inexpensive HCQ, a medication which is conquering COVID-19 in other countries. The urgency of this pandemic, which has taken many lives, crippled our economy, and disrupted our constitutional rights, reinforces the need for this Court to issue a preliminary injunction now, which Defendants do not earnestly contest.

As confirmed by another recent study of thousands of patients at the Henry

Ford Health System in Michigan, HCQ is both very safe and highly effective in treating COVID-19, reducing mortality by 50%. Henry Ford Health System, *Treatment with Hydroxychloroquine Cut Death Rate Significantly in COVID-19 Patients, Henry Ford Health System Study Shows* (July 2, 2020).<sup>1</sup> Dozens of other studies also demonstrate its efficacy as preventive or early treatment for the disease.<sup>2</sup> Countries with underdeveloped health care systems are using HCQ early and attaining far lower mortality than in the United States, where Defendants impede access to HCQ in the Stockpile and elsewhere. *See* Snavely Decl. ¶¶ 28-29 (PageID.359-360).

After Plaintiff filing its motion, Ramin Oskoui, M.D., who is affiliated with the prestigious Johns Hopkins Medicine,<sup>3</sup> explained on national television that “the FDA’s recommendations are really schizophrenic. ... We used [HCQ] in pregnant women. We used it in children. We use it without monitoring in countries for malaria prophylaxis. You may have taken it yourself.” Cardiologist weighs in on risks, benefits of using hydroxychloroquine to treat COVID-19, FOX NEWS (Apr. 24,

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<sup>1</sup> <https://www.henryford.com/news/2020/07/hydro-treatment-study> (last viewed July 20, 2020).

<sup>2</sup> <https://c19study.com/> (last viewed July 20, 2020).

<sup>3</sup> <https://www.hopkinsmedicine.org/profiles/results/directory/profile/0134301/ramin-oskoui> (last viewed July 20, 2020).

2020).<sup>4</sup>

Defendants do not and cannot dispute any of this. Defendants fail to submit affidavits or any other evidence, thereby essentially defaulting on Plaintiff's motion. In their 33-page opposition, Defendants make only one reference to the extensive declaration submitted in support of Plaintiff by Jane Orient, M.D., and agrees with her. Defs.' Memo. 19 (PageID.534). Defendants do not address the numerous public statements by eminent professors and others which emphasize the proven safety of hydroxychloroquine for 65 years. Defendants do not address the overwhelming data and reported studies in support of AAPS's motion, as explained in the declaration by Jeremy Snively in support of Plaintiff. Defendants do not even attempt to justify how they are wasting the nearly 100 million doses of HCQ generously donated to the Stockpile by private companies, to which Defendants block access.

Defendants do not deny their own political and financial conflicts of interest which result in their wrongful interference with HCQ access. The medical science at issue here is simple and less complex than what courts decide every day in medical malpractice cases. Indeed, if a physician failed to recommend HCQ use early for treatment of COVID-19, then a patient harmed by that lack of treatment might have

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<sup>4</sup> <https://www.foxnews.com/transcript/cardiologist-weighs-in-on-risks-benefits-of-using-hydroxychloroquine-to-treat-covid-19> (last viewed July 20, 2020).

a valid cause of action for malpractice which a court would decide without deference to FDA officials, none of whom are practicing medical doctors themselves (“Dr.” Rick Bright’s degree is a Ph.D., not an M.D.).

Yet Defendants maintain that their abrupt revocation of their Emergency Use Authorization (EUA) after the filing of this lawsuit somehow moots it. To the contrary, Defendants continue to block access to HCQ, and Defendants’ falsely disparaging statements while revoking the EUA exacerbated the complained-of interference rather than alleviate it. Defendants initially limited the use of HCQ from the Stockpile to patients *only after* they have been hospitalized, which is unnecessarily late in the progression of the disease. Delaying use of an anti-viral until late in the disease progression obviously reduces its effectiveness, and Defendants’ purported reliance in its revocation on a study that applied HCQ a shockingly late 16.6 days after patients got sick was absurd. Tamiflu, an analogous anti-viral for influenza, is to be administered within 1-2 days of exposure, as AAPS explained and Defendants do not deny. Rather than lift their arbitrary restriction against early use of HCQ, Defendants perpetuate their interference by falsely stating and implying that HCQ should not be used *at any time* to treat COVID, upon which States rely in blocking access.

The results of this arbitrary, wrongful conduct by Defendants have been devastatingly tragic to the American people and our constitutional rights. Countries

that allow public access to HCQ have kept their mortality from COVID-19 to a small fraction of the mortality in the United States. The country-by-country data are readily available on the independent, scientifically managed and widely cited [worldometers.info/coronavirus](https://www.worldometers.info/coronavirus) website, and Plaintiff encourages the Court to peruse its easy-to-read data to observe shockingly high ongoing mortality from COVID-19 in the United States while Defendants impede access to HCQ, in contrast with poorer countries which allow access to HCQ.

Defendants address none of this in their opposition memorandum. Instead, Defendants blithely insist that “this Court has no cause to interfere with decisions of public health officials and scientists responding to COVID-19.” Defs.’ Memo. 2 (PageID.517). Defendants argue that this Court must defer to interference by a handful of bureaucrats in Washington, D.C., regardless of their demonstrated political bias against our President and financial conflicts-of-interest in preferring rivals to hydroxychloroquine. None of Defendants’ arguments justifies their senseless interference with access by the public to hydroxychloroquine, a medication having a 65-year track of safety with numerous studies demonstrating its effectiveness as an *early* treatment against COVID-19 as compiled independently on the [c19study.com](https://c19study.com) website.

The blocking of HCQ access in Oregon, in reliance on the irrational policy of Defendants, disproves their argument that Defendants are not the ones impeding

public access to it. Defs.’ Memo. 21 (PageID.536). The Oregon board of pharmacy, as in many other states, adopted the following regulation about a month ago: “Prescription orders for chloroquine or hydroxychloroquine for the prevention or treatment of COVID-19 infection may only be dispensed if written for a patient enrolled in a clinical trial by an authorized investigator.” Pl.’s Mot., Ex. 10 (PageID.493) Oregon based this ban on the arbitrary position taken by Defendants (*id.*), and the result is that the public cannot obtain access to HCQ in Oregon and most other states, even with a prescription, despite HCQ saving so many lives in foreign countries.

Because there is no possible justification for Defendants’ conduct, they resort to procedural attempts to avert a substantive ruling. Defendants insist that “Dr. Doe’s purported fear of retaliation by a state medical board is, at best, speculative ....” Defs.’ Memo. 13 (PageID.528) (emphasis omitted). But in fact the Michigan Department of Licensing and Regulatory Affairs Enforcement Division (the parent agency of the Michigan Board of Medicine) announced publicly that:

Prescribing hydroxychloroquine or chloroquine without further proof of efficacy for treating COVID-19 ... will be evaluated and may be further investigated for administrative action ....

Joseph Dec. ¶ 3 & Ex. A. And this Michigan agency expressly relies on the FDA EUA for making determinations regarding appropriate prescribing of HCQ:

Dear Licensed Prescribers and Dispensers: This communication is being provided to inform you of a recent guidance that has been issued by the US Food & Drug Administration (FDA) for emergency use of chloroquine phosphate and hydroxychloroquine sulfate.

Joseph Dec. ¶ 4 & Ex. B. There is nothing speculative about Dr. John Doe's fear of retaliation for attempting to prescribe HCQ for his patients.

Ultimately Defendants resort to a generic standing argument, even though virtually everyone is impacted by COVID-19 and thus has standing to object to interference with medication for it. Physicians have standing to assert their own rights and those of their patients, as the U.S. Supreme Court affirmed again as recently last month. Moreover, AAPS provided evidence of injury to itself which Defendants do not even address. To the extent that Defendants want to know who "Dr. John Doe" is, AAPS is willing to reveal his identity in any way that protects him against retaliation. He should not be subjected to harassment and a possible loss of license for trying to save lives amid Defendants' wrongful interference with HCQ.

Finally, it is worth observing that COVID-19 causes higher mortality among the elderly, such as nursing home residents where many lives have been lost to this disease, and there are differing political views about whether to fully protect the elderly and extend their lives. Countries such as in Western Europe having more liberal views about the sanctity of life have been more likely to block access to HCQ, and they have higher mortality rates from COVID-19. In contrast, the more

religiously affiliated countries of Poland, Israel, South Korea, Republic of the Philippines, Turkey, and several in South and Central America have lower mortality rate from COVID-19 as they pursue the more pro-life policy of authorizing HCQ access.<sup>5</sup> President Trump holds and was elected on a pro-life position, and respect for his electoral mandate reinforces the need to enjoin the anti-life interference with HCQ by Defendants.

As explained more fully below, Plaintiff has standing and a valid cause of action, and this Court should grant Plaintiff's motion for a preliminary injunction while denying Defendants' motion to dismiss.

### **STANDARD OF REVIEW**

For purposes of a motion to dismiss, a court assumes the truth of all well-pleaded facts and construes all reasonable inferences in the plaintiff's favor:

Courts must construe the complaint in the light most favorable to the plaintiff[] [and] accept all well-pleaded factual allegations as true. To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim is facially plausible when a plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.

*Matthew N. Fulton, D.D.S., P.C. v. Enclarity, Inc.*, 962 F.3d 882, 2020 U.S. App.

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<sup>5</sup> <http://www.worldometers.info/coronavirus/#countries> (last viewed July 20, 2020).

LEXIS 19232, \*8 (6th Cir. June 19, 2020) (inner quotations and citations omitted). On appeal, the standard of review is *de novo*. *Id.* Regarding AAPS's motion for a preliminary injunction, Defendants argue that a preliminary injunction merely reserves the status quo, but this Circuit uses the same standard to review mandatory and prohibitory injunctions. *Compare* Defs.' Memo. 32 (PageID.547) *with* Pl.'s Memo. 9-10 (PageID.303-304).

### **ARGUMENT**

Defendants' primary argument is to assert that Plaintiff AAPS somehow lacks standing. But amid the COVID-19 pandemic, is there anyone who lacks standing to object to interference with medication for it? Perhaps standing would be lacking for someone who has an unexpected private stockpile of the medication, or someone who has already contracted COVID-19 and survived. That is not Plaintiff AAPS. Anyone who might want or prescribe the medication to treat for COVID-19, and any business impacted by the lack of access to the medication, has standing to object to interference with such access. It is difficult to imagine an issue for which more universal standing exists, and AAPS has both standing and a valid cause of action.

Defendants' interference is ongoing, so there is no mootness. For example, Defendants continue to hoard the Stockpile of HCQ, deny public access to it, and allow it to waste away in warehouses. There is nothing moot about that issue.

Defendants barely object to the motion for a preliminary injunction and

present no evidence against it. Plaintiff's motion should be granted.

**I. THIS COURT HAS JURISDICTION OVER THIS ACTION.**

Defendants raise several jurisdictional arguments to evade this action. These arguments are all meritless.

**A. AAPS has standing.**

Defendants first make boilerplate arguments against standing inappropriate for the pervasive COVID pandemic, about which nearly everyone has standing. Under the facts alleged and the declarations presented by AAPS in support of their motion for a preliminary injunction, AAPS has standing.

Article III standing presents the tripartite test of whether the party invoking a court's jurisdiction raises an "injury in fact" under Article III: (a) a legally cognizable injury (b) that is both caused by the challenged action and (c) redressable by a court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992). Standing doctrine also includes prudential limits, such as the zone-of-interest test, restrictions on raising third-party rights, and a rule against adjudicating generalized grievances more appropriately addressed in the representative branches. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126 (2014). Prudential limits are not jurisdictional, although they can lead a court to decline to consider an issue if the parties are insufficiently adverse: "Even when Article III permits the exercise of federal jurisdiction, prudential considerations demand that the Court insist upon 'that

concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination of difficult constitutional questions.” *United States v. Windsor*, 570 U.S. 744, 760 (2013) (citing *Baker v. Carr*, 369 U.S. 186, 204 (1962)). Lack of adversity is not a problem here.

**1. Not all widely shared grievances are nonjusticiable.**

Defendants’ first argument is that AAPS and its members assert generalized grievances against FDA’s actions. *See* Defs.’ Memo. 18-19 (PageID.533-534). Not all widely shared injuries are prudentially too “generalized” for judicial resolution. *Fed’l Election Comm’n v. Akins*, 524 U. S. 11, 24 (1998) (“where a harm is concrete, though widely shared, the Court has found ‘injury in fact’”). The injuries here are literally life-and-death issues, as well as core constitutional rights like the freedom to practice medicine and to associate; these are not “abstract” or “intellectual” interests. *Id.* at 20. “The kind of judicial language to which the [FDA] points, however, invariably appears in cases where the harm at issue is not only widely shared, but is also of an abstract and indefinite nature – for example, harm to the common concern for obedience to law.” *Id.* at 23 (internal quotations omitted). Defendants’ argument that the injuries that AAPS asserts are too “generalized” is no barrier to review.

**2. AAPS has standing in its own right.**

Membership entities like AAPS can assert their own standing (*i.e.*, injury to

the entity) or associational standing (*i.e.*, injury to its members). *Harkless v. Brunner*, 545 F.3d 445, 458-59 (6th Cir. 2008). Corporations, of course, have rights under the First Amendment. *Mich. State AFL-CIO v. Schuette*, 847 F.3d 800, 805 (6th Cir. 2017). Defendants’ intentional withholding of HCQ’s relief from COVID-19 has already caused AAPS to cancel one conference and threatens its annual conference. *See* Compl. at 23. (PageID.23).<sup>6</sup> That suffices for Article III.

### **3. AAPS has associational standing.**

As indicated, an entity can also have associational standing to assert claims on behalf of its members. *Hunt v. Washington Apple Advertising Comm’n*, 432 U.S. 333, 343 (1977). Here, AAPS’s members have standing – as explained below – and nothing requires their individual participation. *Int’l Union v. Brock*, 477 U.S. 274, 284, 287 (1986) (purely legal actions for injunctive and declaratory relief do not require the participation of individual members.). Moreover, protecting the rights of physicians and patients is germane to AAPS’s mission. *Snavely Decl.* ¶ 3 (PageID.355). As such, associational standing reduces to the question of whether AAPS members have standing.

Indeed, the U.S. Court of Appeals for the Fifth Circuit fully established associational standing by AAPS in an analogous case it brought against the Texas

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<sup>6</sup> As such, Defendants are wrong when they argue that “AAPS does not allege any direct injury to the organization itself.” *Defs.’ Memo.* at 10 (PageID.525).

Medical Board. *Ass’n of Am. Physicians & Surgs. v. Tex. Med. Bd.*, (TMB), 627 F.3d 547 (5th Cir. 2010). There the Fifth Circuit walked through the elements of associational standing based on actions by a state medical board against members of AAPS and held that AAPS has associational standing to sue the medical board for its conduct. *Id.* at 550-53. The situation is conceptually similar here, where AAPS sues Defendants for interfering with the practice of medicine by its members, namely their ability to treat their patients with a full regimen of HCQ for COVID-19.

**a. FDA’s actions have caused redressable injuries to doctors and patients.**

Leaving aside the identity of Dr. Doe, Defendants’ arguments against their causing injury to doctors and patients is meritless. This Court should reject them.

Defendants falsely pretend that they do not interfere with the distribution of HCQ, even though their actions and statements do precisely that. Defendants insist here that “[b]efore, during, and after the EUA’s existence, federal law did not prohibit Dr. Doe from prescribing hydroxychloroquine to a patient.” Defs.’ Memo. 13 (PageID.528). But, in fact, Defendants ***do prohibit*** any access by Dr. Doe and his patients to the HCQ in the Stockpile, despite the donors’ intent for it to be used in treating COVID-19 patients. Moreover, the arbitrary restrictions in Defendants’ EUA was immediately incorporated in this directive by the Federation of State Medical Boards (FSMB) to all medical boards:

[Defendants’ EUA] authorization allows these medications to be prescribed by clinicians for hospitalized adult and adolescent patients “for whom a clinical trial is not available, or participation is not feasible.” Clinicians should avoid prescribing for themselves or their family members and should be aware that deviating from the standard of care *could put their license at risk*.

Compl. at 18 (PageID.18) (emphasis in original); Pl.’s Memo. 22 (PageID.316). Yet Defendants never address this directive by the FSMB to all medical boards, based expressly on Defendants’ improper EUA. There is nothing speculative about Dr. Doe’s fear of retaliation when the FSMB is expressly directing state medical boards to do exactly that and put the medical license of physicians including Dr. Doe at risk based on Defendants’ improper EUA.

Yet Defendants insist that medical board retaliation is “certainly not traceable” to them, Defs.’ Memo. 13 (PageID.528), despite being set forth clearly in AAPS’s Complaint with full citation to the source. The risk of retaliation *is* directly traceable to Defendants, and indeed may be what they intended. Otherwise they would simply make the Stockpile of HCQ available for practicing physicians like Dr. Doe, and his patients. Defendants instead insist on prohibiting all access by Dr. Doe and his patients, and millions of others in similar situations, from having any access to the HCQ Stockpile.

Defendants’ own improper statements in revoking their EUA reinforce how they intend to interfere with access to HCQ. Defendants declared that:

Now, hydroxychloroquine sulfate and chloroquine phosphate can only be used for the treatment of COVID-19 as part of an ongoing clinical trial.

Snively Decl. ¶ 19 (quoting and linking to FDA statement) (PageID.357-358).

Indeed, AAPS's interest in negotiating directly with state medical and pharmacy boards, without FDA's unlawful interference makes this a first-party injury, with no heightened showing of traceability. *Columbia Broadcasting System, Inc. v. U.S.*, 316 U.S. 407, 422-23 (1942); *Haitian Refugee Center v. Gracey*, 809 F.2d 794, 811 n.13 (D.C. Cir. 1987) (no "independent need.... [for] third party standing since the legal right ,, not to be injured by unauthorized agency action ... was their own"); Second Snively Decl. ¶ 6.

Defendants' own opposition brief broadly credits Defendants for directing the Nation amid the coronavirus pandemic, so their contradictory argument rings hollow in pretending that they are not impacting the ability of Dr. Doe to treat patients with a full regimen of HCQ. Defendants imply near the end of their brief that they alone have "the background, competence, and expertise to assess public health," and that the Court should defer to them on that basis. Defs.' Memo. 33 (PageID.548). But in arguing against standing, Defendants try to downplay their significance and influence. Which is it? In fact, of course, Defendants try to and do exercise enormous influence over state medical boards and pharmacies, and Defendants' disparagement of and interference with access to HCQ has been devastating to AAPS members and

their patients, thereby giving AAPS standing.

Defendants rely on two Sixth Circuit decisions, neither of which are applicable here. In *Fednav, Ltd. v. Chester*, 547 F.3d 607 (6th Cir. 2008), the standing defect was that Plaintiff was not clear as the injury caused by defendants' actions. But Plaintiff AAPS is clear here: its members cannot access HCQ, and AAPS's own conferences have been damaged by the lack of availability of HCQ as a preventive or early treatment. In *Nat'l Rifle Ass'n of Am. v. Magaw*, 132 F.3d 272 (6th Cir. 1997) (cited by Defs.' Memo. 13, 15 (PageID.528, 530)), there was no direct injury to the association, as there is here in the interference with AAPS's holding of its conferences. Snively Decl. ¶¶ 22-27 (PageID.358-359) Moreover, virtually everyone is affected by the COVID-19 pandemic and the interference by Defendants with access to HCQ in the Stockpile and elsewhere, in contrast with the challenge in *Nat'l Rifle Ass'n* to a particular gun statute.

In short, unless this Court requires AAPS to identify Dr. Doe, Defendants' arguments against physician-based standing lack merit.

**b. AAPS need not identify its members.**

Defendants argue that, to show associational standing, AAPS must identify at least one member who has standing. *See* Defs.' Mem. at 11 (PageID.526). The requirement to identify a member does not apply, however, when *all* members have standing. *Summers v. Earth Island Institute*, 555 U.S. 488, 498 (2009). Given

Defendants’ arguments about generalized grievances, their argument is specious: if *everyone* will benefit, there is no need to assure that court that *someone* will benefit.<sup>7</sup>

Even if *Summers* applied, the concern there was a lack of specificity. Here, by contrast, Dr. Doe is identified with sufficient specificity for an investigator with subpoena authority to identify him. He practices within the Western District of Michigan, has some patients who live in Kalamazoo, is a member of AAPS, is male, and has sought to prescribe a full regimen of HCQ. That is not millions, thousands, or even hundreds of possibilities, but merely one. The *Summers* standard for specificity is fully satisfied, and Defendants could have made a discovery request here with accompanying confidentiality, if their concern were bona fide.<sup>8</sup> Moreover, Dr. Doe is by no means the only AAPS physician member affected by FDA’s

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<sup>7</sup> Defendants also cite *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 235 (1990), but the concern there was the need to assure the court that at least one petitioner would benefit from the relief provided. There is no question that multiple AAPS members and AAPS itself would benefit from the requested relief.

<sup>8</sup> In a recent decision by the U.S. Supreme Court, multiple physicians remained confidential throughout the entire litigation without any difficulty, and hundreds of references to the physicians as “Doe \_\_\_” pervade its oral argument and opinions. *June Med. Servs. L.L.C. v. Russo*, 207 L.Ed.2d 566 (U.S. 2020) (decided June 29, 2020). Dr. Doe here should be allowed to have a modicum of the same privacy as he attempts to save lives amid a climate of politically based retaliation against physicians who prescribe or speak out in support of hydroxychloroquine. Note also that the identity of the “whistleblower” behind the impeachment of President Trump was not disclosed, and Defendants’ argument that Dr. Doe here must reveal his identity to defend a position of Trump is ironic.

actions. *See* Second Snively Decl. ¶¶ 4-5.

AAPS has justifiably withheld the name of its member “Dr. John Doe” to protect this practicing physician, who serves Michigan residents, against retaliation with respect to the highly politicized issue of HCQ. In Michigan, anyone from anywhere can file an anonymous complaint over the internet with the Michigan medical board,<sup>9</sup> for any improper reason. Given the unfortunate political ramifications of this litigation, Dr. Doe would surely be subjected to multiple potentially career-ending – and certainly expensive – politically motivated disciplinary actions against him if his name were publicly revealed in connection with this lawsuit. He need not give up his professional career or endure such inhuman harassment for merely for trying to do the right thing: serve Michigan patients without interference by Defendants with access to HCQ.

Thus, unlike in *Summers*, there is potential retaliation against Dr. Doe if he is unmasked in this litigation. First, Michigan officials have stated publicly their intention to discipline physicians who prescribe HCQ contrary to the (unjustified) policy of Defendants. *See* Introduction, *supra*. Second, any disgruntled opponent of President Trump could – and some would – file complaints against Dr. Doe. At least with respect to physician members, the risk of incurring enforcement exposure

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<sup>9</sup> [https://www.michigan.gov/lara/0,4601,7-154-89334\\_63294\\_63384\\_70218-339092--,00.html](https://www.michigan.gov/lara/0,4601,7-154-89334_63294_63384_70218-339092--,00.html) (last viewed July 20, 2020).

provides an exception to the need to identify individual members.

Defendants' citations to Sixth Circuit decisions are even more off-point. In *Waskul v. Washtenaw Cty. Cmty. Mental Health*, 900 F.3d 250 (6th Cir. 2018), the holding was that "all [of the association's] named members had received apparently adequate administrative hearings at the time the complaint was filed [which] foreclosed the Association's ability to now seek fresh notices and hearing rights for all its unnamed members." *Id.* at 257-58. It was not the lack of naming members which caused that case to be dismissed, but the lack of injury to the members who were named. Defendants' other two citations to Sixth Circuit decisions concern rules about an anonymous *plaintiff*. Defs.' Memo. 12 (PageID.527). But there is nothing anonymous about Plaintiff AAPS, so those rules do not apply here. Rather, AAPS has sued on behalf of itself and its members as it is fully entitled to do.

**c. Withholding Dr. Doe's identity is easily cured.**

In any event, Dr. Doe is willing to testify at a preliminary injunction hearing with suitable protections against harassment, or otherwise provide his name in a way that reasonably protects him, such as a protective order establishing an attorneys' eyes-only disclosure. Any legitimate objection to Dr. Doe's confidentiality, thus, could be easily cured. As such, his Doe status does not provide a basis for denying a preliminary injunction or for dismissing the Complaint for want of standing. But Defendants do not pose their objection for a legitimate reason: their own arguments

about generalized grievances reveal that they do not doubt *some* injury.

**4. AAPS has third-party standing for its physician members.**

As an alternative to resolving the need to identify a member for associational standing under *Summers*, this Court could find that AAPS has third-party standing to assert Dr. Doe's injuries. The Snively declaration establishes that Dr. Doe *exists*, and AAPS meets the three-part test for third-party standing: (1) AAPS has its own constitutional standing, (2) AAPS has a close relationship with Dr. Doe, and (3) the threat of enforcement or harassment hinders Dr. Doe's initiating his own suit. *See Kowalski v. Tesmer*, 543 U.S. 125, 128-30 (2004). Under the circumstances, AAPS has third-party standing to seek redress for its physician-members' injuries.

**5. Physicians – and thus AAPS – have standing to assert patients' rights.**

Defendants also argue that AAPS cannot assert standing for patients. AAPS physician members are themselves subject to COVID-19, and thus are themselves patients. So right off the bat Defendants' argument that AAPS cannot assert claims on behalf of patients is misplaced here. This is not a case about a medical condition which the physician himself never has; rather, physicians are at more risk of COVID-19 than their own patients are, and thus physicians have valid claims on behalf of themselves as both physicians and patients themselves. In any event, physicians have standing to assert their patients' interests under the *Kowalski* test, *supra.*; *see also Crossen v. Breckenridge*, 446 F.2d 833, 840 (6th Cir. 1971) ("*Griswold v.*

*Connecticut* ... establishes the standing of a doctor to assert the alleged rights of his patients in his own behalf”). Finally, standing is “transitive” through membership organizations: A potential plaintiff with standing who belongs to a membership group gives the large group standing to assert the standing that the member could assert. *See N.Y. State Club Ass’n, Inc. v. New York*, 487 U.S. 1, 9 (1988). Because AAPS’s physician members have standing to assert their patients’ interests, so too does AAPS.

**B. Even if APA review were unavailable, the APA’s waiver of sovereign immunity would authorize non-APA review.**

Although Defendants argue that the APA does not apply to its EUA actions, *see* Defs.’ Memo. 24-25 (PageID.539-540), that does not remove the APA’s waiver of sovereign immunity: “The APA’s waiver of sovereign immunity applies to any suit whether under the APA or not.” *United States v. City of Detroit*, 25 F. App’x 384, 388-89 (6th Cir. 2002) (internal quotations omitted) (collecting cases). Accordingly, this Court has jurisdiction for “declaratory, injunctive or mandamus relief” against Defendants, notwithstanding their status as federal officers and offices.

**C. This action is not moot.**

Defendants argue that FDA’s rescission of the EUA moots this litigation. *See* Defs.’ Mem. at 21-23 (PageID.536-538). This action is not moot, however, both because this Court could vacate or amend the rescission to “unmoot” the action and

because FDA's rescission itself included actionable statements.

**1. This Court can vacate or modify FDA's rescission.**

Mootness is an Article III jurisdictional issue. *Allen v. Wright*, 468 U.S. 737, 750 (1984). As AAPS explained and Defendants do not directly dispute, rescission is a form of agency action that a reviewing court could vacate or amend. *See* Pl.'s Memo. 33-34 (PageID.327-328). As such, rescission alone cannot moot this case because it is possible that this Court will vacate or amend the rescission.<sup>10</sup>

**2. Statements in FDA's rescission would remain reviewable, even if rescission itself were moot.**

Even if Defendants were correct – and they are not – that the relevant statutes make FDA's EUA unreviewable, *see* Section II.A, *infra*, this Court still could review statements within those EUA actions that are not themselves EUA actions. *See* Pl.'s Memo. 22 (PageID.316). Nothing in the relevant statutes even arguably prevents judicial review of agency actions *outside* of EUA actions, and Defendants have not argued otherwise. Defendants' arguments about mootness and commitment to their discretion are, therefore, insufficient to preclude this Court's granting some relief from FDA's actions.

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<sup>10</sup> As indicated in Section II.D, *infra*, the fact that the rescission post-dates the filing of AAPS's complaint is no barrier to relief.

## **II. AAPS STATES CLAIMS ON WHICH THIS COURT CAN GRANT RELIEF.**

Defendants devote more than a third of their argument to insisting that Plaintiff AAPS has not stated a cause of action. Defs.’ Memo. 23-30 (PageID.538-545). Under Defendants’ reasoning, they can falsely disparage HCQ with impunity, deny access to HCQ in the Stockpile while it wastes away amid a pandemic, issue an irrational EUA and a senseless revocation, without any cause of action against it. No precedents support Defendants’ argument, and of course a cause of action exists to challenge Defendants’ arbitrary, harmful conduct.

Notably, Defendants do not argue that there is anything implausible about AAPS’s allegations. Defendants do not dispute in any way the allegations by AAPS of their political bias against President Trump, and their conflicts of interest with respect to more expensive medications which are rivals to HCQ. Nor do Defendants argue against construing all reasonable inferences of those biases in favor of AAPS’s causes of action.

Instead, Defendants make an incorrect argument that their conduct is somehow “excepted by statute from judicial review” under the Administrative Procedure Act (APA). Exemptions from judicial review are rare and narrowly construed, but Defendants insist that everything they have done as alleged by AAPS is someone outside the scope of accountability in court under the APA. Their argument is breathtaking and without basis. The APA fully applies to Defendants’

conduct and AAPS has stated a valid cause of action under it.

Moreover, Defendants cannot argue for lack of judicial review of their alleged infringement of constitutional rights, violations, and Defendants briefly argue for dismissal of those claims on entirely different grounds. Defs.’ Memo. 28-30 (PageID.543-545). Even though numerous in-person conferences have been cancelled nationwide, including one by Plaintiff AAPS, for lack of the availability of preventive medication for COVID-19, Defendants pretend that “neither the EUA nor its revocation” impacted this. Defs.’ Memo. 28 (PageID.543). That raises an issue of fact unsuitable for granting a motion to dismiss. Similarly, Defendants resort to factual arguments about whether it committed an equal protection violation by prohibiting use of HCQ outside of hospitals, thereby denying access by the elderly in nursing homes. Defs.’ Memo. 30 (PageID.545). Defendants’ motion to dismiss is insufficient on the law and should be denied.

**A. FDA’s actions are reviewable.**

Defendants argue that the relevant statutes commit FDA’s EUA actions to agency discretion. *See* Defs.’ Mem. at 24-25 (PageID.539-540). They are wrong under the APA, under pre-APA review, and under constitutional review.

**1. The relevant statutes do not bar APA review.**

By its terms, the APA’s preclusion of review provision applies only “to the extent” that a statute precludes review. *See* 5 U.S.C. § 701(a). As it applies here, that

does not include actions taken by FDA actors to whom Defendant Azar has delegated authority to act for him: “Actions under the authority of this section *by the Secretary*, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.” 21 U.S.C. § 360bbb-3(i) (emphasis added). In addition, FDA statements on a website – if false and actionable, *see* Pl.’s Memo. 22 (PageID.316) – are neither taken by Defendant Azar nor taken pursuant to § 360bbb-3. As such, FDA’s actions remain subject to APA review.

## **2. The relevant statutes do not bar pre-APA review.**

In any event, “nothing in the subsequent enactment of the APA altered the [pre-existing] doctrine of review.” *Chamber of Commerce of the United States v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996); *see Duncan v. Muzyn*, 833 F.3d 567, 578 (6th Cir. 2016) (recognizing the ongoing vitality of pre-APA review). As Prof. Davis put it shortly after the APA’s enactment, when review is cut off under the Act (*i.e.*, the APA), “[t]he result is that the pre-Act law continues.” Kenneth Culp Davis, *Nonreviewable Administrative Action*, 96 U. PA. L. REV. 749, 776 (1948). Under that pre-APA review, “if an official acts solely on grounds which misapprehend the legal rights of the parties, an otherwise unreviewable discretion may become subject to correction.” *Arenas v. United States*, 322 U.S. 419, 432 (1944). As such, AAPS would have an action for judicial review and abuse of discretion, even if the APA action were unavailable.

### 3. The relevant statutes do not bar constitutional review.

Finally, even if the relevant statutes bar APA review, AAPS still can pursue its claims under the Constitution. *Webster v. Doe*, 486 U.S. 592, 603-04 (1988) (citing cases). Under that authority, “where Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear.” *Webster*, 486 U.S. at 603. No such intent is clear here: instead, Congress – at best – sought to preclude APA review under 5 U.S.C. § 701(a)(2).

#### B. Whether under the APA or pre-APA review, FDA’s actions were improper.

As indicated in the prior section, judicial review is available under either the APA or pre-APA review, as well as under the Constitution. Because the standards for arbitrary-and-capricious review overlap with rational-basis review, Pl.’s Memo. 34-35 (PageID.328-329), the arguments here also apply the equal-protection claim

Defendants – or at least their counsel – argue repeatedly that HCQ remains commercially available, Defs.’ Memo. 1, 2, 7, 13-14, 18 (PageID.516-517, 522, 528-529, 533), but that misses the point in at least two respects. First, counsel’s unsworn statements do not qualify as evidence. *Frazier v. United States*, 335 U.S. 497, 503 (1948). Second, these repeated claims of commercial availability ignore the fact that FDA’s false, statutorily unauthorized, and reviewable statements – which are not backed by any data – have created a legal impediment to commercial use of HCQ for COVID-19 prescriptions. See Pl.’s Memo. 21-22 (PageID.315-316); cf. 21 USCS

§ 360bbb-3(e)(2)(C) (precluding actions that limit availability of approved drugs for approved uses when issuing an EUA for an unapproved use). Because states have acted based on FDA's unauthorized statements disparaging HCQ, the *FDA statements* would be reviewable, even if FDA's *EUA actions* were not. *See* Pl.'s Memo. 22 (PageID.316); *cf. Block v. Meese*, 793 F.2d 1303, 1309 (D.C. Cir. 1986) (government statements reviewable if they *de facto* cause third-party action).

### **1. FDA acted arbitrarily and capriciously.**

In response to AAPS's argument that FDA acted arbitrarily and capriciously – and, thus, also without a rational basis – Defendants dispute AAPS's arguments that the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-399i (FFDCA), measures drug safety for a drug (*i.e.*, not a disease) and that FDA lacks statutory authority to condition access to stockpiled HCQ on participation in a clinical study. In doing so, Defendants implicitly concede that FDA's safety-for-COVID argument makes no sense for *prophylactic* use of HCQ because the patient does not have COVID-19. *See* Pl.'s Memo. 38-39 (PageID.332-333). Because Defendants cannot hide behind their committed-to-discretion argument, *see* Section II.A, *supra*, AAPS states a claim for judicial review of FDA's actions to preclude prophylactic use of HCQ from the EUA, both initially and when FDA decided to terminate the EUA's provisions for hospitalized COVID-19 patients.

In addition, FDA's actions constitute an abuse of discretion because: (1) they

waste an invaluable resource in a pandemic; (2) they are based on bias, *D.C. Fed’n of Civic Ass’ns v. Volpe*, 459 F.2d 1231, 1246 (D.C. Cir. 1971); *Utica Packing Co. v. Block*, 781 F.2d 71, 78 (6th Cir. 1986) (“the appearance of bias or pressure may be no less objectionable than the reality”); and (3) FDA disparaged the safety and efficacy of HCQ for COVID-19 without any data to support negative statements.<sup>11</sup> While Defendants seek this Court’s deference to their purported expertise, the FDCA recognizes practicing physicians as the relevant experts with respect to off-label uses of approved drugs. *See* Pl.’s Memo. 10 (PageID.304). In our federalism, a patient is entitled to choose his or her doctor and that doctor’s advice, with state supervision and without input from FDA bureaucrats. Defendants’ lack of authority for the clinical-trial provision is laid out in the next section.

Even discretion has its bounds: Defendants could not lawfully limit distribution to people living in odd-numbered zip codes or people who are not sick. Such limitations would exceed Defendants’ statutory authorization, just as Defendants’ limitation of use of an anti-viral medication (HCQ) to patients who are late in the progression of the disease (*i.e.*, hospitalized) or inaccessible to a clinical trial (where placebos are used) were arbitrary limitations. These limitations

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<sup>11</sup> Unlike rational-basis review, review of agency action is based on the record before the agency. Compare *Motor Vehicle Mfrs. Ass’n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 50 (1983) (APA); *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) (pre-APA) with *F.C.C. v. Beach Commc’ns, Inc.*, 508 U.S. 307, 315 (1993).

predictably resulted in the vast majority of stockpiled HCQ never being used and wasting away in warehouses. These limitations were senseless, or intentionally designed to make HCQ appear unsuccessful. Defendants had no statutory authority for that, and AAPS has stated a valid cause of action to overturn senselessly crippling limitations by Defendants on use of HCQ.

Defendants argue that the EUA was issued by the FDA's Chief Scientist, not by the biased Dr. Rick Bright of BARDA whose opposition to HCQ is documented. Defs.' Memo. 26-27 (PageID.541-542). But the EUA was addressed to Dr. Bright, and expressly states that he requested it. EUA, at 1 (PageID.474). "Sources tell [the news website] STAT, too, that even high-ranking FDA officials were kept out of the loop in this instance" of issuing the EUA. Nicholas Florko, *Why was an obscure federal bureaucrat involved in Trump's emergency hydroxychloroquine authorization?* STAT NEWS (Apr. 24, 2020).<sup>12</sup> These are issues of fact which make Defendants' motion to dismiss inappropriate.

## **2. FDA exceeded its statutory authority.**

In several respects, FDA's actions exceeded Defendants' statutory authority, which is reviewable under both the APA and pre-APA review.

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<sup>12</sup> <https://www.statnews.com/2020/04/24/why-rick-bright-involved-hydroxychloroquine/> (last visited July 20, 2020).

**a. FDA lacks statutory authority for its clinical-trial requirement.**

As set forth in the Complaint and explained in AAPS’s opening brief in support of its motion, Defendant FDA exceeded its statutory authority in connection with the EUA by requiring even hospitalized COVID-19 patients to enroll in a clinical trial, where they might receive a placebo instead of HCQ. Defendants cite 21 U.S.C. § 360bbb-3(d), (e)(1)(B)(2), (e)(2) as authority for the clinical-trial requirement, Defs.’ Memo. 26 (PageID.541), but none of those subsections provide the claimed authority. First, § 360bbb-3(d) is silent on the issue, and § 360bbb-3(e)(1)(B)(2) concerns drugs that are not approved. Since HCQ is an approved drug, the authority that Defendants claim must reside in § 360bbb-3(e)(2). That paragraph consists of three subparagraphs, the second and third of which relate to labeling and FDA’s duty not to restrict approved uses for approved drugs. *See* 21 U.S.C. § 360bbb-3(e)(2)(B)-(C). The last subparagraph incorporates by reference for unapproved uses of approved drugs some of the criteria that apply or can apply to unapproved drugs. *See* 21 U.S.C. § 360bbb-3(e)(2)(A) (incorporating 21 U.S.C. § 360bbb-3(e)(1)(A)(i)-(ii) and 360bbb-3(e)(1)(B)(iii)-(iv)). Of the four incorporated criteria, two concern information that must be provided to health care professionals and patients, 21 USCS § 360bbb-3(e)(1)(A)(i)-(ii), and one concerns “recordkeeping and reporting ... with respect to the emergency use of the product,” *id.* § 360bbb-3(e)(1)(B)(iv). The last provides that “the Secretary may establish,” *id.* § 360bbb-

3(e)(2)(A), “Appropriate conditions with respect to collection and analysis of information concerning the safety and effectiveness of the product with respect to the use of such product during the period when the authorization is in effect and a reasonable time following such period.” 21 U.S.C. § 360bbb-3(e)(1)(B)(iii). That is far from statutory authority to impose clinical trials, and AAPS respectfully submits that it is not “appropriate” to impose clinical trials – which deny some patients access to the drug – as a condition to “fill” a prescription.<sup>13</sup>

**b. FDA lacks statutory authority to limit off-label uses, based on perceived safety.**

Just as Defendants conflate their EUA authority for unapproved drugs with their authority for unapproved uses of approved drugs, Defendants suggest that FDA approves drugs as safe for specific conditions, rather than safe for patients, because the FFDCA “expressly limits determinations of safety and effectiveness to the conditions of use on the proposed label, including the diseases the drug purports to treat.” (citing, but not quoting, 21 U.S.C. § 355(b), which refers broadly to “safe for use,” not “safe for the use on the proposed label”). FDA’s authority to condition the use of a new drug approval is irrelevant here. HCQ is extremely safe and was approved by the FDA in 1955 as safe *without limitation* as to the condition being

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<sup>13</sup> The authority restrict EUAs is much greater for *unapproved* drugs, 21 U.S.C. § 360bbb-3(e)(1), which is irrelevant for HCQ.

treated. Moreover, because HCQ is an approved drug, physicians – not the FDA or federal government – make the informed decision of when to use an approved drug for off-label (*i.e.*, unapproved) uses: “[O]nce a [drug] product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling.” 59 Fed. Reg. 59,820, 59,821-22 (Nov. 18, 1994) (internal quotation marks omitted, alterations in original). Defendants obfuscate here with a silly example of potentially prescribing chemotherapy drugs for headaches without comparing the labels for such drugs versus the label for HCQ or suggesting why any physician would take that step. Defendants’ absurd example disparages HCQ’s demonstrated safety and efficacy for early or prophylactic use against COVID-19 and insults not only physicians but also the many patients whose lives Defendants have worsened or ended prematurely.

### **3. FDA’s actions are “not in accordance with the law.”**

In response to AAPS’s argument that FDA violated the anti-discrimination provisions of Section 1557 of the Affordable Care Act, Defendants, 42 U.S.C. § 18116, Defendants argue – correctly – that the “EUA and the Stockpile fall outside [the] definition” of “Health program or activity” promulgated at 45 C.F.R. § 92.4. Defs.’ Memo. 27 (PageID.542). But that is not the test, and Defendants do not credibly dispute that FDA’s actions unlawfully discriminated against the elderly.

As AAPS explained, Section 1557 applies not only to a “health program or

activity” that receives federal funds but also to “any program or activity that is administered by an Executive Agency or any entity established under this title.” 42 U.S.C. § 18116(a). Section 1557 is 18116 of Title 42 and the Stockpile is organized at § 247d-6b of Title 42. Defendants thus meet the second clause, even if they do not meet the first.

**C. AAPS states a claim under the First and Fifth Amendments.**

Plaintiff AAPS has stated straightforward and valid claims under the First Amendment, for infringement on their ability to associate by holding conferences (Count III), and under the Fifth Amendment, for Defendants’ infringement on the equal protection clause by limiting HCQ use to hospitalized patients (Count I). Both AAPS claims should survive Defendants’ motion to dismiss, which relies on factual speculation inappropriate for a motion to dismiss.

**1. Defendants’ actions chill First Amendment rights.**

Interference with HCQ as a prophylaxis or early treatment has made association at conferences, football games, religious services, and even school all but impossible. Defendants’ interference with access to HCQ, despite its successful use as a prophylaxis against malaria, has the same sort of chilling effect on constitutional rights which courts routinely enjoin. Note that it does not really matter how effective HCQ is as a prophylaxis against COVID-19, although numerous

studies show that it is highly effective.<sup>14</sup> What matters here is whether Defendants' interference with access to HCQ causes a chilling effect on associating through conferences and otherwise, and it plainly does. That is unconstitutional conduct by Defendants which must be enjoined.

Defendants cite a leading Sixth Circuit precedent on this issue, but then misapply it. AAPS is not asserting any claim to intimate association. AAPS simply wants to be able to hold its traditional conferences amid the COVID-19 pandemic, and that requires removal of impediments to safe, already approved medication. Defendants, perhaps trying to cripple Trump rallies, have crippled AAPS's conferences too by interfering with the availability of HCQ as a prophylaxis and early medication for COVID-19.

This claim by AAPS fits squarely within case law on freedom of association:

This First Amendment freedom to gather in association for the purpose of advancing shared beliefs is protected by the Fourteenth Amendment from infringement by any State. *Kusper v. Pontikes*, 414 U.S. 51, 57; *Williams v. Rhodes*, 383 U.S. 23, 30-31. See also *NAACP v. Alabama ex rel. Patterson*, 357 U.S. 449, 460.

*Democratic Party of United States v. Wisconsin*, 450 U.S. 107, 121-22 (1981). If a prophylaxis is needed to gather during a pandemic, then interference with access to that prophylaxis despite its safety and inexpensive cost constitutes an infringement

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<sup>14</sup> <https://c19study.com/> (last viewed July 20, 2020).

on the right to gather. Currently, Trump's own rallies are being impeded by Defendants' interference with public access to HCQ, and Plaintiff AAPS has just as much a right to gather as voters for Trump do. Defendants' cited authority does not justify their interference with access to a prophylaxis for COVID-19, HCQ. *Saieg v. City of Dearborn*, 641 F.3d 727, 741 (6th Cir. 2011) (concerning a restriction merely to leafletting without any impact on freedom of association).

Defendants do not deny that a lack of availability of a prophylaxis for COVID-19 is impeding the right of people to gather, and when Plaintiff AAPS's allegations are taken as true then they have stated a cause of action.

## **2. Defendants violated the Due Process Clause's Equal Protection component.**

Defendants' complained-of conduct prevented nursing home patients – the elderly – from obtaining timely access to HCQ for COVID-19. As pointed out in AAPS's opening brief and not rebutted by Defendants, nursing homes have been ravaged by COVID-19 and account for roughly 50% of the mortality. There is no plausible rational basis for Defendants to block access to HCQ for nursing home patients, while allowing it for hospitalized patients, as Defendants did in the EUA. While Defendants have since terminated their allowing of HCQ for most hospitalized patients now also, that does not cure their equal protection violation of continuing to allow HCQ use for some people while denying it for others, including denying it for many people who need it the most.

In *Ctr. for Bio-Ethical Reform, Inc. v. Napolitano*, 648 F.3d 365 (6th Cir. 2011) (cited by Defs.’ Memo. 17 (PageID.532)), the court dismissed a claim based on an allegation of “targeting Plaintiffs for disfavored treatment on account of Plaintiffs’ viewpoint on certain political issues.” *Id.* at 379. That is obviously not the type of equal protection claim being asserted here. As set forth in the Complaint, Plaintiff AAPS alleges that:

98. The EUA impermissibly discriminates based on a patient’s hospitalization status, illness status, and access to clinicals trial, without a rational basis for this discrimination. ...

100. With respect to patients who wish to use HCQ, and medical professionals who wish to prescribe HCQ for its prophylactic effect to prevent becoming infected with the COVID-19 virus, the EUA’s limitation to hospitalized patients with COVID-19 lacks a rational basis for a drug that FDA already has found to be safe.

Compl. at 21 (PageID.21). This plainly states a valid cause of action for an equal protection violation based on a lack of a rational basis for Defendants’ actions, as explained in Plaintiff’s opening brief, Pl.’s Memo. 38-42 (PageID.332-336), and not rebutted by Defendants.

Defendants criticize the request by AAPS that access to HCQ in the Stockpile be opened to the entire public, even without a prescription, but that relief may be necessary to cure the equal protection violation. *All* Americans have an equal right to the Stockpile, which contains HCQ donated without discrimination about who

could receive it. Millions of Americans, including higher proportions of minorities, do not visit physicians for examinations, and thus cannot obtain a prescription for HCQ. “[T]he proportion of U.S. adults with a primary care physician fell from 77% in 2002 to 75% in 2015.” Linda Carroll, *Declining numbers of Americans have a primary care provider*, REUTERS (Dec. 16, 2019).<sup>15</sup> “40% of Americans ... say they ‘skipped a recommended medical test or treatment in the last 12 months due to cost.’” Bruce Japsen, *Poll: 44% Of Americans Skip Doctor Visits Because Of Cost*, FORBES (Mar 26, 2018).<sup>16</sup> The lack of early treatment can result in hospitalization, and “[a]ccording to the Centers for Medicare and Medicaid Services, Black Americans enrolled in Medicare were hospitalized with [COVID-19] at rates nearly four times higher than their white counterparts.” Maria Godoy, *Black Medicare Patients With COVID-19 Nearly 4 Times As Likely To End Up In Hospital*, NPR (June 22, 2020).<sup>17</sup>

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<sup>15</sup> <https://www.reuters.com/article/us-health-pcp-trends/declining-numbers-of-americans-have-a-primary-care-provider-idUSKBN1YK1Z4> (last viewed July 20, 2020).

<sup>16</sup> <https://www.forbes.com/sites/brucejapsen/2018/03/26/poll-44-of-americans-skip-doctor-visits-due-to-cost/#567546786f57> (last viewed July 20, 2020).

<sup>17</sup> <https://www.npr.org/sections/health-shots/2020/06/22/881886733/black-medicare-patients-with-covid-19-nearly-4-times-as-likely-to-end-up-in-hosp> (last viewed July 20, 2020).

**D. A court can grant relief – and especially interim relief – on claims outside the pleadings.**

Defendants argue that this Court cannot grant relief outside the pleadings and that AAPS, instead, needed to amend its pleadings. *See* Defs.’ Memo. 31 (PageID.546). Defendants are simply wrong.

At the outset, a court can address evidence and issues outside the pleadings. *See* FED. R. CIV. P. 15(b). Moreover, the ubiquitous last line of most complaints – requesting “[s]uch other relief as may be just and proper,” Compl. at 24 (PageID.24) – is ubiquitous for a reason. “the complaint requested ‘such other and further relief as the Court may deem just and proper[,’ which] permits a district court to award damages for breach of contract even when the plaintiff has not pled a contract claim.” *People for the Ethical Treatment of Animals, Inc., v. Gittens*, 396 F.3d 416, 421 (D.C. Cir. 2005); *accord* FED. R. CIV. P. 54(c) (“[e]very other final judgment should grant the relief to which each party is entitled, even if the party has not demanded that relief in its pleadings”); *see also Lockhart v. Leeds*, 195 U.S. 427, 436-37 (1904) (“[t]here is nothing in the intricacy of equity pleading that prevents the plaintiff from obtaining the relief under the general prayer, to which he may be entitled upon the facts plainly stated in the bill”); *Bemis Brothers Bag Co. v. U.S.*, 289 U.S. 28, 34 (1933) (“rule is now general that at a trial upon the merits the suitor shall have the relief appropriate to the facts that he has pleaded, whether he has prayed for it or not”). There is plenty of time for the pleadings to catch up, FED. R.

Civ. P. 15(b); *see also Griffin v. Cty. Sch. Bd.*, 377 U.S. 218, 226-27 (1964), but in the meantime AAPS's motion for a preliminary injunction presents urgent issues that require this Court's attention now.

### **III. AAPS IS ENTITLED TO A PRELIMINARY INJUNCTION.**

Defendants say surprisingly little – less than 2.5 pages – in opposition to AAPS's motion for a preliminary injunction. Maybe that is not surprising after all. In fact, not much can be said by Defendants in defense of their false and misleading statements about HCQ, and their attempt to waste nearly 100 million doses of it donated to the Stockpile. Defendants cannot contest the overwhelming evidence, presented in two declarations in support of Plaintiff's motion, against their irrational position and statements concerning HCQ. Defendants cannot justify their arbitrary actions in interfering with access to HCQ. Defendants cannot explain why they limited use of HCQ until after hospitalization, when anti-viral medication is most effective when given soon after exposure to the virus.

Instead, Defendants make a cut-and-paste type argument that they supposedly acted within their discretion. But Defendants have plainly abused their discretion in withholding the HCA Stockpile and interfering with access to it. There is no plausible argument that wasting nearly 100 million doses of donated HCQ, amid a pandemic, is a proper exercise of discretion. Defendants do not, and cannot, argue that their specific actions were within their proper discretion. Defendants make no

serious argument about the likelihood of success by AAPS on the merits of its case.

**A. If this Court’s rejects FDA’s procedural defenses, this Court should grant interim relief because FDA has not otherwise disputed AAPS’s entitlement to that relief.**

Defendants make procedural arguments to try to prevent this Court from ordering it to correct Defendants’ false statements made after the filing of the Complaint in this case. If those procedural arguments fail, Defendants have raised no serious defense against this Court’s granting the requested preliminary injunction.

AAPS sued on June 2, 2020, and Defendants made false statements on June 16, wrongly disparaging HCQ in furtherance of their wrongful conduct alleged in the Complaint. Even though Defendants’ false statements against HCQ were a continuation of their interference with HCQ as alleged in the Complaint, Defendants insist that this Court is powerless to order Defendants to correct their post-Complaint statements. Defendants’ argument is silly, and their citations do not support it. Of course this Court can order Defendants to correct false statements by them made after the filing the Complaint where, as here, the statements are an extension of wrongdoing alleged in the Complaint.

Defendants misplace reliance on *Colvin v. Caruso*, 605 F.3d 282 (6th Cir. 2010), quoting it for the proposition that AAPS has “no grounds to seek an injunction pertaining to allegedly impermissible conduct not mentioned in [its] original complaint.” *Id.* at 300. That Sixth Circuit decision, however, ***reversed*** a denial of a

motion for a preliminary injunction by a prisoner in a case relating to religious freedom, and allowed amendment of the complaint. *Id.* Here, no such amendment is necessary because AAPS specifically requested in its complaint that Defendants “enjoined from impeding the distribution, sale or purchase of HCQ by adult members of the public during the COVID-19 pandemic.” Compl. ¶ 118(C)(iii). Statements made by Defendants which falsely disparage HCQ, including those made post-Complaint on June 16, are well within the scope of the relief sought by AAPS in the Complaint and can be enjoined by this Court. Defendants’ other cited authority did not involve a preliminary injunction and is completely inapposite. *See Bates v. Green Farms Condo. Ass’n*, 958 F.3d 470 (6th Cir. 2020) (cited by Defs.’ Memo. 31 (PageID.546)). Defendants’ repeated reliance on a Supreme Court decision reversing a preliminary injunction against the Navy for using sonar to guide submarines is misplaced also, given the sharp contrast between the many deaths caused by COVID-19 without access to HCQ compared with the speculative harm to an underwater species from sonar. *Winter v. NRDC, Inc.*, 555 U.S. 7 (2008) (cited by Defs.’ Memo. 9, 30-31 (PageID.524, 545-546)).

Defendants doubt that AAPS will be harmed if a preliminary injunction is not granted. In less than merely three weeks since AAPS filed its motion, the American mortality from COVID-19 has shot up from 370 per million residents to more than 430 per million, as reported by the respected, independent

worldometers.info/coronavirus website cited above. But how does this pandemic affect AAPS? AAPS's conferences are ruined by the lack of access to a prophylaxis, as attested by the declaration of Jeremy Snavelly in support of the motion, and AAPS members are impeded in their ability to prescribe a full regimen of HCQ, as also set forth in his declaration. The importance of early treatment by HCQ is explained by Jane Orient, M.D., in her declaration also submitted in support of the motion, and AAPS members are themselves denied these benefits unless a preliminary injunction issues. Defendants rebut none of this. Michigan's own above-quoted public statements in reliance on false statements by Defendants, to threaten investigations of physicians who prescribe HCQ, demonstrate the imminent harm to AAPS members if the preliminary injunction is not granted. Also, Defendants' wasting of the HCQ Stockpile harms all Americans, including AAPS members. Nothing speculative about any of this, as the body counts mount. A preliminary injunction would help avert this harm, which far exceeds that of poorer countries allowing access to HCQ.

As AAPS argued in its opening brief, a preliminary injunction to block the wasting of the HCQ Stockpile and end Defendants' interference with HCQ access would clearly be in the public interest. (Pl.'s Memo. 47-48 (PageID.341-342). Defendants provide no reason or evidence to the contrary, and merely argue that an injunction "would have a dramatic and deleterious effect on HHS's authority to

respond to public health emergencies.” Defs.’ Memo. 32 (PageID.547). Under that logic, Defendants say they should *never* be enjoined, no matter how badly they behave. But that is not a valid argument against an injunction. Defendants needed to show why an injunction in this case might harm the public, and Defendants cannot make that showing. Ordering Defendants to correct their false statements, stop interfering, and stop wasting the HCQ Stockpile have a positive public benefit, without any negative impact.

Defendants rely on a widely criticized, and non-precedential, concurring opinion by Chief Justice John Roberts in denying an application by a church to hold services in California. *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613 (2020) (quoted by Defs.’ Memo. 32 (PageID.547)) (Roberts, C.J., concurring in denial of application). No other justice joined Chief Justice Roberts’ concurrence, and four dissented from it. Moreover, nothing in that concurrence justifies *withholding and blocking* access to life-saving medication, HCQ. The existence of pandemic, on which Defendants rely, weighs *against* Defendants’ interference with access to HCQ. The greater the pandemic, the less the justification for Defendants to allow the Stockpile to waste away rather than be opened to the public.

The canard that a court should not second-guess decisions by publicly elected officials has no merit here. The decision-makers at the FDA are not publicly elected

and, as career civil servants, are protected against political accountability and even removal by the elected president. The decision-maker Rick Bright, Ph.D., has filed a whistleblower action while he publicly criticizes our elected president. He does not practice medicine, and none of the officials at Defendant agencies does. It does not require any specialized expertise to compare the mortality of patients who receive HCQ as an early treatment to those who do not. Likewise, an expert is not necessary to realize that allowing nearly 100 million doses of HCQ to rot away in a government warehouse is an abuse of discretion. *See, e.g. Robinson v. Wash. Metro. Area Transit Auth.*, 774 F.3d 33, 39-40 (D.C. Cir. 2014) (“You don’t need a weatherman to know which way the wind blows.”) (Merrick Garland, J.) (quoting BOB DYLAN, *Subterranean Homesick Blues*, on BRINGING IT ALL BACK HOME (Columbia Records 1965)).

Contrary to Defendants’ assertion, Plaintiff AAPS does not want to override any decisions by Defendants which are properly within their discretion and not arbitrary or capricious. Instead, AAPS seeks to enjoin the abuse of discretion by Defendants in acting on political and financial motivation to interfere with access by the public to life-saving medication. Discretionary authority in the hands of Defendants does not justify their irrational interference with access to HCQ, or their wasting nearly 100 million doses of the donated medication. Discretionary authority is not a blank check or immunity from judicial review. Defendants are simply wrong

in implying that they can do whatever they want, and even waste a stockpile of lifesaving medication, without any accountability in court.

Defendants' irrational interference with access to HCQ and Defendants' wasting of the Stockpile of HCQ should be enjoined. Plaintiff's motion for a preliminary injunction should be granted.

**B. FDA's interference with HCQ correlates with anti-life policies in other countries, contrary to President Trump's position.**

For most morbidities from disease, the wealthy United States and Western Europe lead the world in having the lowest mortality rates. Yet for COVID-19, these wealthy regions of the world have the highest mortality rates. COVID mortality correlates with the countries' interference with public access to HCQ, as explained in the Snavelly declaration supporting Plaintiff's motion, Snavelly Decl. ¶¶ 28-29 (PageID.359-360), and not denied by Defendants' opposition.

An additional correlation is clear as more data emerge: interference with HCQ access is itself correlated with countries skeptical about the sanctity of life. Abortion is prohibited throughout much of the world but is legal in many places in Western Europe and the United States. These are roughly the same countries where there is interference with access to HCQ, and the mortality from COVID is the highest.<sup>18</sup>

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<sup>18</sup> As displayed by the independent, constantly updated [worldometers.info/coronavirus](https://worldometers.info/coronavirus) website, the six highest mortality rates for COVID-19 among major countries are all in Western Europe, all countries which have legalized abortion: Belgium, U.K., Spain, Italy, Sweden, and France, all having

In contrast, Poland prohibits abortion, and authorizes use of HCQ to treat COVID. Danish Medicine Agency, *COVID-19: Facts about chloroquine and hydroxychloroquine* (Apr. 7, 2020).<sup>19</sup> Polish chemists even showed the world in March how to cheaply synthesize HCQ. *Polish chemists show how to cheaply synthesise drug used to treat COVID-19*, THE FIRST NEWS (Mar. 26, 2020).<sup>20</sup> As a result of its pro-life rather than anti-life policies, Poland has only one-tenth the COVID mortality rate among its residents compared with other countries in Western Europe.<sup>21</sup> The lower mortality rate in Poland is consistent with the pro-life policies chosen by its voters, while the higher mortality in most countries of Europe is arguably consistent with skepticism by voters there toward the sanctity of life. COVID mostly afflicts the elderly and the vulnerable, so perhaps this correlation should not be surprising.

Defendants' interference with HCQ in nationwide is contrary to the pro-life position of President Trump, on which the American people elected him. The

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mortality rates from COVID-19 ten times higher than that of Poland which authorizes use of HCQ.

<sup>19</sup> <https://laegemiddelstyrelsen.dk/en/news/2020/covid-19-facts-about-chloroquine-and-hydroxychloroquine/> (last viewed July 20, 2020).

<sup>20</sup> <https://www.thefirstnews.com/article/polish-chemists-show-how-to-cheaply-synthesise-drug-used-to-treat-covid-19-11508> (last viewed July 20, 2020).

<sup>21</sup> <https://www.worldometers.info/coronavirus/#countries> (last viewed July 20, 2020).

officials within Defendant agencies who have imposed this irrational policy against HCQ are opponents of President Trump and presumably the positions on which he was elected. But such arbitrary interference should be enjoined by this Court so that President Trump can implement the policies for which he was elected.

### **CONCLUSION**

This Court should enter the requested preliminary injunction against Defendants to broaden meaningful public access to HCQ pending this litigation's resolution. If the Court requires identifying Dr. Doe, Plaintiff requests leave to identify him confidentially.

This Court should deny Defendants' motion to dismiss or, alternatively, grant leave to amend.

Dated: July 20, 2020

Respectfully submitted,

/s/ Lawrence J. Joseph

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**CERTIFICATE OF COMPLIANCE**

This memorandum complies with the word limit of Local Civil Rule 7.2(b)(i) because – excluding the parts exempted by that rule – the memorandum contains 10,790 words. The word count was generated using Microsoft Word 2016.

Dated: July 20, 2020

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